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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,169	03/15/2002	Eric Marechal	213993US0PCT	8971

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

FIELD, TAMMY K

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/28/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,169

Applicant(s)

MARECHAL ET AL.

Examiner

Tammy K. Field

Art Unit

1645

-- Th MAILING DATE of this communication appears on th cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Responsive to Preliminary amendment filed on October 22, 2002, Applicants have canceled Claims 1-3 and 10-11. Claims 12-17 are new claims added. New claims have support in original claims of PCT/FR00/00658 in replaced Article 34 amendment claims 1-12. Instant Claims 34-9, and 12-17 are presently under examination.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Applicants' claim of priority for the foreign application date of March 19, 1999 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-9 and 12-17 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

Art Unit: 1645

in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims encompass a method for screening and selecting antiparasitic agents, herbicides or combination thereof comprising incubating a test substance with MGDG synthase or plant plastid membrane and measuring specific enzyme activity. Subsequent claims encompass a pharmaceutical composition comprising an MGDG synthase inhibitor and method of treating an animal, including human, having an apicomplex parasite, herbicide comprising a MGDG synthase inhibitor and method comprising treating a plant with the herbicide.

The instant specification discloses the isolation and characterization of the enzyme, MGDG synthase and the ability of some chemical compounds to either inhibit or protect the enzyme's activity *in vitro*. The instant specification does not show the correlation between MGDG synthase or the compounds that inhibit or protect MGDG synthase and antiparasitic agents. Furthermore, the instant specification is silent in regard to the use of any of these compounds in conjunction with an MGDG synthase inhibitor in a pharmaceutical composition for treating an animal, including a human, having an apicomplex parasite or in a pharmaceutical composition for a method of treating a plant with a herbicide comprising MGDG synthase inhibitor.

McFadden, G.I. *et al.* 1996. (Nature 381: 482) teach relatedness of Toxoplasma and Plasmodium plastids to algae and the probable role of said plastids to herbicide sensitivity, but is silent to higher plant genes or gene products involved, *e.g.* MGDG synthase and the relation these parasites have to higher plants, *e.g.* spinach, cucumber plastid envelope membranes. This

Art Unit: 1645

questions the relation between antiparasitic agents and using MGDG synthase in higher plants and apicomplex parasites for screening and selecting for antiparasitic agents.

Merechal, *et al.* 1997. (*Physiologia Plantarum* 100(1): 65-67) teach that very little is known about the enzymes that catalyze glycerolipids biosynthesis in higher plants at page 66, paragraph 1. Merechal, *et al.* 1997 further teach all experiments on MGDG synthase from spinach and cucumber led to the same conclusion that, despite its importance for chloroplast membrane biogenesis, MGDG synthase is only a minor envelope protein (representing probably less than 0.05% of total envelope protein, while the envelope proteins correspond to 1 to 2% of the total protein content of the chloroplast) at page 70, paragraph, 5.

Miege, C. and Merechal, E. 1999. (*Plant Phy. and Biochem.* 37: 795-808) teach MGDG synthase in the plastids of higher plants is one known enzyme involved in the conversion of the intermediate DAG to membrane glycerolipids and that there appears to be alternate known pathways and enzymes available for production of membrane glycerolipids, if MGDG inhibition occurs at page 798 (see Figure 2-B). Miege, C. and Merechal, E. also teach the function of the MGDG enzyme *in vivo* is still a matter of debate at page 798, paragraph 1. Miege, C. and Merechal, E. further teach the study of Marechal *et al.* 1995. (*J. Biol. Chem.* 270: 5714-5722), incorporated herein by reference, wherein the study demonstrated that envelope MGDG synthase activity does not have the same affinity for all molecular species of DAG. Miege, C. and Merechal, E. teachings further question the use of the instant claims MGDG synthase for screening antiparasitic agents and/or herbicides for MGDG synthase inhibition and method of using a MGDG synthase inhibitor as pharmaceutical compositions against parasites of animals, *i.e.* humans, and furthermore, the use a MGDG synthase inhibitor as a herbicide of plants.

Art Unit: 1645

In view of the nature of the invention and in view of the state of the art with respect to pharmaceutical composition comprising an MGDG synthase inhibitor for treating an animal or human having an apicomplex parasite, it is determined that it would require undo experimentation to practice the invention commensurate in scope with the claimed subject matter. Additionally, a method comprising treating a plant with the herbicide, an MGDG synthase inhibitor, it is determined that it would require undo experimentation to practice the invention commensurate in scope with the claimed subject matter.

4. Claims 12-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of "pharmaceutical composition comprising a MGDG synthase inhibitor" because it is unclear from the specification what applicant intends. It is additionally unclear the relationship between screening and selecting antiparasitic agents and/or herbicides and a MGDG synthase inhibitor for use in a pharmaceutical composition for treating an animal having an apicomplex parasite and/or use as a herbicide.

Clarification is required in order to overcome this rejection.

Status of the Claims

5. No claims are allowed.

Art Unit: 1645

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447.

The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Tammy K. Field
November 26, 2003



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600